FORM PTO-1390 (REV 3/2001)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

DATE: March 13, 2002

EXPRESS MAIL LABEL NO. EL496231049US

ATTORNEY DOCKET NO. 47890/MEG

U.S. APPLICATION NO. 10/088439

INTERNATIONAL APPLICATION NO	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/DE00/03160	September 12, 2000	13 September 1999

TITLE OF INVENTION
AORTIC BALLOON OCCLUSION AORTA

APPLICANT(S) FOR DO/EO/US
DOARE, Michel

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (Unexecuted)
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5))

Items 13 to 20 below concern document(s) or other information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A FIRST preliminary amendment..
16. ☐ A SECOND or SUBSEQUENT preliminary amendment..
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ SMALL ENTITY Assertion. Applicant(s) and any other associated with it/them under 37 CFR § 1.27(a) are a small entity.
20. ☒ Certificate of Mailing by Express Mail.
21. ☒ Other items or information: Extra Set of Drawings

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY DOCKET NO
10/088439	PCT/DE00/03160	47890/MEG

21. The following fees are submitted:		CALCULATIONS	PTO USE ONLY
☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO:	$1,040.00		
☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$890.00		
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	$740.00		
☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)	$710.00		
☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4)	$100.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =		$ 890	
Surcharge of **$130** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		$ 130	

Claims	Number Filed	Number Extra	Rate		
Total Claims	20-20=	0	X $18	$ 0	
Independent Claims	2-3=	0	X $84	$ 0	
Multiple dependent claim(s) (if applicable)			+ $280	$	
TOTAL OF ABOVE CALCULATIONS =				$ 1020	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				$	
SUBTOTAL =				$ 1020	
Processing fee of **$130** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$	
TOTAL NATIONAL FEE =				$ 1020	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property				$	
TOTAL FEES ENCLOSED =				$ 1020	
Note (1): **The basic national fee must be paid when filing this application. The 20-month time limit (37 CFR § 1.494) and 30-month time limit (37 CFR § 1.495) are not extendable.**				Amount to be: refunded	$
				charged	$

a. ☒ A check in the amount of **$ 1020** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **03-1728**. A duplicate copy of this sheet is enclosed.

NOTE (2): **Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

Mark Garscia
CHRISTIE, PARKER & HALE
P.O. Box 7068
Pasadena, CA 91109-7068

CUSTOMER NUMBER: 23363

By _____
Mark Garscia
Reg. No. 31,953

CKS PAS420962.1-*-3/13/02 2:32 PM

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL NO. EL496231049US

Applicant	:	Michel Doaré
Application No.	:	To be Assigned
Filed	:	Herewith
Title	:	AORTIC BALLOON OCCLUSION AORTA
Docket No.	:	47890/MEG/J191

PRELIMINARY AMENDMENT

Post Office Box 7068
Pasadena, CA 91109-7068
March 13, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Commissioner:

Please amend the specification as follows:

In the Specification

After the title please add the following:

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority of PCT/DE00/03160 filed September 12, 2000 which claims priority of EP 99117905.2 filed September 13, 1999.

Replace the paragraph beginning on page 5, line 13 with the following new paragraph:

Outside of cannula tube 3, suitable fittings for the supply of dilatation liquid, shutoff valves and controls are assigned to the conduits formed by the lumina 7, 8 in order to dilate the occlusion balloons 5, 6 during the occlusion of the ascending aorta 2, and to return them into the non-dilated state. These means and devices are not illustrated in detail. They are well-known.

Docket No. 47890/MEG/J191

Replace the paragraph beginning on page 6, line 8 with the following new paragraph:

Lumen 11 leads also through both occlusion balloons 5, 6 and ends at 15 (fig. 3) on the proximal side of the occlusion balloon 5. It can be blocked through a gate valve 16 which is indicated schematically in fig. 3.

In the Claims:

1. An aortic balloon occlusion cannula for the occlusion of the ascending aorta during cardiac surgeries comprising

- a cannula (1) containing several lumina that are separated from one another, said cannula carrying two dilatable occlusion balloons (5, 6) positioned at a distance from each other, one of said balloons being neighbored to the proximal end of the cannula which faces the heart and each of said balloons being connected to its own lumen (7, 8) which enables its dilatation in independence from the other balloon,

- said cannula (1) containing additionally at least one further lumen (11) that is connected on the proximal side of the proximal occlusion balloon and on the distal side of the other distal occlusion balloon (6) to the lumen of the aorta and which is adapted to be connected to an extracorporal blood supply device (13), and

- valve means (16) that are assigned to the part of this additional lumen (11) which ends on the proximal side of the proximal occlusion balloon (5).

2. The balloon occlusion cannula according to claim 1 characterized by the two occlusion balloons (5, 6) being mounted in such a way that they are movable towards each other in an axial direction.

3. (Amended) The balloon occlusion cannula according to claim 1 characterized by the fact that it contains a further separated lumen (9) forming a conduit ending on the proximal side of the proximal occlusion balloon (5) and serving for instance for provoked cardiac arrest and/or aspiration.

4. (Amended) The balloon occlusion cannula according to claim 1 characterized by the fact that the cannula (1) contains in the area between the two occlusion balloons (5, 6) a least one opening (14) that leads into this area and that is connected to its own lumen in the cannula (1).

5. (Amended) The balloon occlusion cannula according to claim 1 characterized by the fact that it contains a cannula tube (3) which shows in the area of the two occlusion balloons (5, 6) a generally straight section (17) and shows a second section (18) that goes off the ascending aorta (2) at right angles when the cannula (1) is inserted into the ascending aorta.

6. (Amended) The balloon occlusion cannula according to claim 1 characterized by the fact that it contains a cannula tube (3) that shows at least in the area of the occlusion balloons (5, 6) a curved section (17) shaped according to the shape of the ascending aorta.

7. (New) The balloon occlusion cannula according to claim 3 characterized by the fact that the cannula (1) contains in the area between the two occlusion balloons (5, 6) a least one opening (14) that leads into this area and that is connected to its own lumen in the cannula (1).

8. (New) A method of attaching a vein bypass to an ascending aorta of a heart of a body, comprising:

providing a cannula having two balloons and several lumina that are separated from one another, wherein the two balloons include a first dilatable occlusion balloon to be located proximal to the heart and a second dilatable occlusion balloon to be located distally to the heart, and wherein the plurality of separate lumens include a first lumen connected to the first

balloon to enable dilation of the first balloon, a second lumen connected to the second balloon to enable dilation of the second balloon independent of the first balloon, and a third lumen that opens to the ascending aorta through an opening on a distal side of the second balloon;

connecting the third lumen to an extracorporal blood supply device;

positioning the two balloons in the ascending aorta such that the two balloons are positioned at a distance from each other along the ascending aorta;

dilating the two balloons;

performing the anastomoses at the ascending aorta between the two balloons; and

deflating the two balloons and removing the cannula from the body.

9. (New) The method of claim 8 wherein the third lumen also has an opening on a proximal side of the first balloon and has a valve located between the openings of the third lumen.

10. (New) The method of claim 9 further comprising opening the valve to supply blood to the heart through the opening on the proximal side of the first balloon after dilating the first balloon.

11. (New) The method of claim 8 wherein the several lumina include a separate conduit in addition to the first, second and third lumens, that has an opening on the proximal side of the first balloon.

12. (New) The method of claim 11, further comprising supplying heart protection solution to the heart through the conduit.

13. (New) The method of claim 11, further comprising aspirating liquid through the conduit.

14. (New) The method of claim 11, further comprising perfusing the aortic root through the conduit.

15. (New) The method of Claim 8 wherein the several lumina include a separate lumen, in addition to the first, second and third lumens, opening to an area between the two balloons.

16. (New) The method of Claim 15 further comprising aspirating liquid through the separate lumen that opens to the area between the two balloons.

17. (New) The method of Claim 15 further comprising supplying liquid through the separate lumen that opens to the area between the two balloons.

18. (New) The method of Claim 11 wherein the several lumina include a separate lumen, in addition to the first, second and third lumens, opening to an area between the two balloons.

19. (New) The method of Claim 18 further comprising aspirating liquid through the separate lumen that opens to the area between the two balloons.

20. (New) The method of Claim 18 further comprising supplying liquid through the separate lumen that opens to the area between the two balloons.

In the Abstract:

Please add the attached abstract.

REMARKS

The specification has been amended to correct numbering and spelling errors. The claims have been amended to remove multiple dependencies. New Claims 7-20 have been added to more completely cover certain aspects of the invention. An Abstract is attached.

Docket No. 47890/MEG/J191

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By _____
Mark Garscia
Reg. No. 31,953
626/795-9900

MEG/cks

Docket No. 47890/MEG/J191

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Paragraph beginning on page 5, line 13 has been amended as follows:

Outside of cannula tube 3, suitable fittings for the supply of dilatation liquid, shutoff valves and controls are assigned to the conduits formed by the lumina 7, [9] 8 in order to dilate the occlusion balloons 5, 6 during the occlusion of the ascending aorta 2, and to return them into the non-dilated state. These means and devices are not illustrated in detail. They are well-known.

Paragraph beginning on page 6, line 8 has been amended as follows:

Lumen 11 leads also through both occlusion balloons 5, 6 and ends at 15 (fig. 3) on the proximal side of the occlusion balloon 5. It can be blocked through a gate valve 16 which is indicated schematically in fig. 3.

In the Claims:

3. (Amended) The balloon occlusion cannula according to claim 1 [~~or 2~~] characterized by the fact that it contains a further separated lumen (9) forming a conduit ending on the proximal side of the proximal occlusion balloon (5) and serving for instance for provoked cardiac arrest and/or aspiration.

4. (Amended) The balloon occlusion cannula according to [~~one of the preceding claims~~] claim 1 characterized by the fact that the cannula (1) contains in the [~~are~~] area between the two occlusion balloons (5, 6) a least one opening (14) that leads into this area and that is connected to its own lumen in the cannula (1).

5. (Amended) The balloon occlusion cannula according to [~~one of the preceding claims~~] claim 1 characterized by the fact that it contains a cannula tube (3) which shows in the area of the two occlusion balloons (5, 6) a generally straight section (17) and shows a second

section (18) that goes off the ascending aorta (2) at right angles when the cannula (1) is inserted into the ascending aorta.

6. (Amended) The balloon occlusion cannula according to [~~one of the claims 1 to 4~~] claim 1 characterized by the fact that it contains a cannula tube (3) that shows at least in the area of the occlusion balloons (5, 6) a curved section (17) shaped according to the shape of the ascending aorta.

Docket No. 47890/MEG/J191

AORTIC BALLOON OCCLUSION AORTA

ABSTRACT OF THE DISCLOSURE

An aortic balloon occlusion cannula for the occlusion of the ascending aorta during cardiac surgery includes a cannula containing several lumina that are separated from one another. The cannula carries two dilatable occlusion balloons positioned at a distance from each other, one of the balloons being neighbored to the proximal end of the cannula which faces the heart and each of the balloons being connected to its own lumen which enables its dilation in independence from the other balloon. The cannula additionally contains at least one further lumen that is connected on the proximal side of the proximal occlusion balloon and on the distal side of the distal occlusion balloon to the lumen of the aorta and is adapted to be connected to an extracorporal blood supply device. A valve is assigned to the part of this additional lumen which ends on the proximal side of the proximal occlusion balloon.

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PATENT

#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL NO. EL496231083US

Applicant	:	Michel Doaré
Application No.	:	10/088,439
Filed	:	March 13, 2002
Title	:	AORTIC BALLOON-OCCLUSION CANNULA (as amended)
Docket No.	:	47890/MEG/J191

PRELIMINARY AMENDMENT

Post Office Box 7068
Pasadena, CA 91109-7068

Commissioner of Patents and Trademarks
Washington, D.C. 20231-0001
Box PCT

June 6, 2002

Commissioner:

In the Title:

Please change title to:

AORTIC BALLOON-OCCLUSION CANNULA

REMARKS

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

Respectfully submitted,

CHRISTIE, PARKER & HALE, LLP

By _____
Mark Garscia
Reg. No. 31,953
626/795-9900

MEG/cks

Docket No. 47890/MEG/J191

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Title:

AORTIC [~~BALLOON OCCLUSION AORTA~~] BALLOON-OCCLUSION CANNULA

CKS PAS439887.1-*-6/6/02 9.21 AM

2/pats

Aortic Balloon Occlusion Aorta

The invention concerns an aortic balloon cannula for the occlusion of the ascending aorta during cardiac surgery.

An arteriosclerotically altered aorta represents a problem in the field of cardiac surgery. It occurs in almost all patients who suffer from calcification of the coronary vessels or in patients with valvular diseases. It is necessary to insert an aortic cannula into the ascending aorta in order to connect for instance a patient, who undergoes a bypass operation, to the extracorporal circulation (heart-lung machine). The blood circulation is separated from the heart by clamping the ascending aorta towards the heart that is proximally, with a metal clamp, which is attached at right angles. There is, however, the danger of a detachment of particles or plaques from the wall of the ascending aorta which are transported by the blood flow especially into the blood vessels of the head and therefore into the brain. This leads to embolies, which appear clinically often in form of neurological failures (cerebral infarction).

An aortic balloon occlusion is known from the DE 19 15 933 A1. It is used to avoid the risks going along with aortic clamping at right angels during the extracorporal circulation that is applied during cardiac surgeries. It includes an occlusion cannula that can be inserted into a catheter. Its lumen is connected on both sides to a dilatable balloon, which allows closing the ascending aorta from the inside by means of a balloon occlusion during the

ischemic time without an aortic clamping at right angles. A similar aortic occlusion cannula has also been described in the USA 5,334.142 especially in connection with cardiopulmonary resuscitation.

These balloon occlusions, however, do not solve the problematic of other dangers, which can also lead to a calcified embolie as a result of an arteriosclerotic ascending aorta.

In order to be able to suture the vein bypass to the aorta during a bypass surgery, the aorta has to be clamped wih a metal clamp over a certain length in the area of the suture. There is a considerable risk of embolie connected with this therapy. In order to provoke a cardiac arrest, it is also necessary to infuse a cardioplegic substance into the ascending aorta. It is possible that plaques are separated if a cardioplegic conduit is inserted especially for this purpose into the ascending aorta.

The object of this invention is to offer a solution to the above mentioned problem and to create an aortic balloon occlusion cannula for the occlusion of the ascending aorta during surgeries. This aortic balloon occlusion cannula is to reduce the danger of the separation of calcified plaques from the calcified ascending aorta and to guarantee a careful treatment of the aorta during the surgery.

As a solution to this task, the balloon occlusion cannula shows, according to the invention, the features of patent claim 1.

The new aortic cannula permits the clamping of the

ascending aorta from the inside by means of a dilatable occlusion balloon. In addition, the cannula carries a second occlusion balloon that is positioned in a certain distance from the first balloon. It is able to separate an area from the perfusion. This area is determined by the distance between the two balloons. It serves then for the suture of the vein bypasses. With this, the dangerous tangential clamping of an aortic area is avoided. At the meantime, the aortic root perfusion can be performed by means of a proximal conduit in order to reduce the ischemic time.

The new cannula can also function as a supply of the heart protecting solution to the heart, or it can enable an aspiration. The advantage of the new aortic cannula is that the aorta is clamped from the outside not tangentially nor at right angles, and that the conduit for the heart protecting solution does not have to be inserted through an extra entry into the aorta. Thus, the operating field becomes clearer as well because no other conduits and clamps interfere with the operating field.

Further embodiments of the new balloon occlusion cannula are subject of subclaims.

The illustration shows an example of the subject of the invention. The following figures show:

Fig. 1 a balloon occlusion cannula according to the invention in situ is an schematic illustration,

Fig. 2 the cannula according to fig. 1 cut lengthways of line II-II of fig. 1 in a schematic illustration and

Fig. 3 the balloon occlusion cannula according to fig. 1 in an axial cut, in a side view and in a very simplified illustration.

The aortic balloon occlusion cannula, which is generally marked by a 1, is to occlude the ascending aorta indicated at 2, during cardiac surgeries. It contains a cannula tube 3 that is made out of an elastic material. This material enables the introduction of the cannula tube 3, while adapting to the required curvatures, into the ascending aorta through a corresponding incision at 4 (fig. 3).

Cannula tube 3 can also be pre-shaped according to the curvature of the ascending aorta. Two dilatable occlusion balloons 5 and 6 that are positioned in a distance from each other, are mounted on the cannula tube 3. The first balloon 5 is positioned at the proximal end of the cannula tube 3, neighboring the heart, while the other balloon 6 ought to be in a distance of approximately 20 to 30 mm from the balloon 5.

Both occlusion balloons 5, 6 consist of an elastic dilatable plastic, e.g. polyethylene which provides sufficient stiffness and consistency of shape in order to guarantee a secure closing of the ascending aorta 2. The diameter of the two balloons 5, 6 is adapted to the inner diameter of the ascending aorta 2 and its size is about 30 mm. The axial length of each of the two occlusion balloons is about 1.5 to 2 cm or more. Both occlusion balloons 5, 6 can be positioned on the cannula tube 3 either fixed or in such a way that they are movable towards each other in order to enable an adaption to the anatomic situation in each individual case.

Cannula 1 contains several separated lumina. They form independent conduits and can be distinguished as for instance indicated schematically in fig. 2.

A first lumen 7, indicated in fig. 3 by a chain dotted line, leads to the first occlusion balloon 5 and permits its dilatation by means of suitable dilatation liquid (physiologic salt solution). A second lumen 8, shown in fig. 3 by a double chain dotted line, leads to the second occlusion balloon 6 and enables its dilatation by means of the corresponding dilatation liquid.

Outside of cannula tube 3, suitable fittings for the supply of dilatation liquid, shutoff valves and controls are assigned to the conduits formed by the lumina 7, 9 in order to dilate the occlusion balloons 5, 6 during the occlusion of the ascending aorta 2, and to return them into the non-dilated state. These means and devices are not illustrated in detail. They are well-known.

A third lumen 9 defines a conduit crossing both occlusion balloons 5,6. It ends at 10 on the proximal side of the occlusion balloon 5 facing the heart. It permits to supply the heart with a heart protecting solution or for instance to aspire liquid from the part of the ascending aorta that is proximal of the occlusion balloon. The conduit formed by lumen 9 contains a shut-off organ 90 that permits the control of the supply of the heart protecting solutions as required. The internal diameter of the lumen 9 is approximately 3 mm (to name an approximate size).

A wider and larger lumen 11 is enclosed by cannula tube 3. It is connected to the lumen of the distal part of

the ascending aorta when the cannula is inserted in the aorta 2 over an opening 12 in the wall of the cannula 3. Lumen 11 forms a blood conduit that is, as indicated schematically in fig. 1, connected to a heart-lung machine 13 which maintains the circulation extracorporaly. The diameter of the opening 12 is 10 mm or more.

Lumen 11 leads also through both occlusion balloons5, 6 and ends at 15 (fig. 3) on the proximal side of the occlusion balloon 5. It can be blocked through a gate valve 16 which is indicated schematically in fig. 3.

The discharge flow-through for the aortic root perfusion is approximately 500 to 800 ml per minute.

The wall of cannula 3 shows in the area that is located between the occlusion balloons 5, 6, an opening 14 that is connected to a further, separated lumen in the tube of cannula 3. This lumen forms its own conduit which is indicated with dots in fig. 3 at 140. The conduit can be used to aspire blood from the area located between the two occlusion balloons 5, 6 or to fill this area with liquid.

The tube of cannula 3 shows a generally straight or, according to the aorta, curved section 17 which is located within the ascending aorta 2. From this section leads a section 18 approximately at right angles outside of the aorta. The opening 12 is still located within the height of the straight section 17, that is little above of the curvation at the junction between both sections 17, 18 in order to guarantee that it lies securely in the ascending aorta when the cannula is inserted.

When the new cannula is used - this cannula can also be named aortic endoclamping cannula with double balloon technique and integrated cardioplegic cannula - the proximal occlusion balloon 5 is dilated after the insertion of cannula 1 in the ascending aorta, while gate valve 16 is closed. Thus the ascending aorta 2 is blocked. The conduit defining lumen 9 enables at 10 the supply of a cardioplegic solution to the heart while the body circulation is supplied with blood from the heart-lung machine 13 over lumen 11 and opening 12. At this time the anastomoses located close to the heart are sutured.

Then the valve gate 16 is opened which enables the supply of the heart with blood over lumen 11. The second occlusion balloon 6 is dilated, so that the ascending aorta has a second barrier at this position. The limited area of the ascending aorta between the two balloons 5, 6 is opened and provided with „punched out" anastomotic holes, whereupon the anastomoses are sutured. One of them is shown in fig. 3 at 19.

Upon the termination of this measure, the two occlusion balloons are deflated, and the organism is trained to function without the heart-lung-machine. Cannula 1 and, if existent, a catheter that surrounds the cannula is taken out of the ascending aorta 2, whereupon the aorta is sutured.

Claims:

1. An aortic balloon occlusion cannula for the occlusion of the ascending aorta during cardiac surgeries comprising

   - a cannula (1) containing several lumina that are separated from one another, said cannula carrying two dilatable occlusion balloons (5,6) positioned at a distance from each other, one of said balloons being neighbored to the proximal end of the cannula which faces the heart and each of said balloons being connected to its own lumen (7,8) which enables its dilatation in independence from the other balloon,

   - said cannula (1) containing additionally at least one further lumen (11) that is connected on the proximal side of the proximal occlusion balloon and on the distal side of the other distal occlusion balloon (6) to the lumen of the aorta and which is adapted to be connected to an extracorporal blood supply device (13), and

   - valve means (16) that are assigned to the part of this additional lumen (11) which ends on the proximal side of the proximal occlusion balloon (5).

2. The balloon occlusion cannula according to claim 1 characterized by the two occlusion balloons (5,6) be-

ing mounted in such a way that they are movable towards each other in an axial direction.

3. The balloon occlusion cannula according to claim 1 or 2 characterized by the fact that it contains a further separated lumen (9) forming a conduit ending on the proximal side of the proximal occlusion balloon (5) and serving for instance for provoked cardiac arrest and/or aspiration.

4. The balloon occlusion cannula according to one of the preceding claims characterized by the fact that the cannula (1) contains in the are between the two occlusion balloons (5,6) a least one opening (14) that leads into this area and that is connected to its own lumen in the cannula (1).

5. The balloon occlusion cannula according to one of the preceding claims characterized by the fact that it contains a cannula tube (3) which shows in the area of the two occlusion balloons (5,6) a generally straight section (17) and shows a second section (18) that goes off the ascending aorta (2) at right angles when the cannula (1) is inserted into the ascending aorta.

6. The balloon occlusion cannula according to one of the claims 1 to 4 characterized by the fact that it contains a cannula tube (3) that shows at least in the area of the occlusion balloons (5,6) a curved section (17) shaped according to the shape of the ascending aorta.

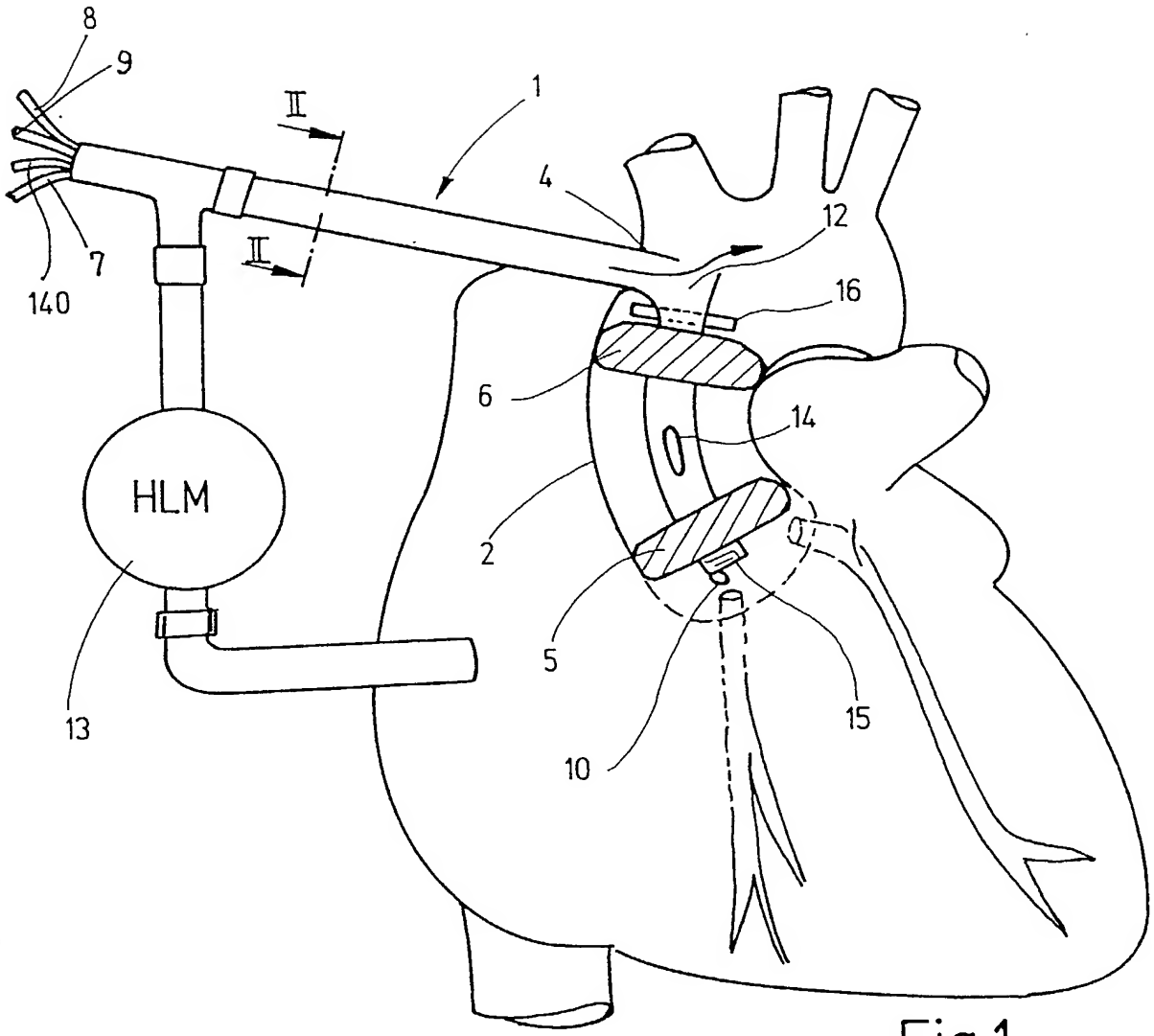

Fig.1

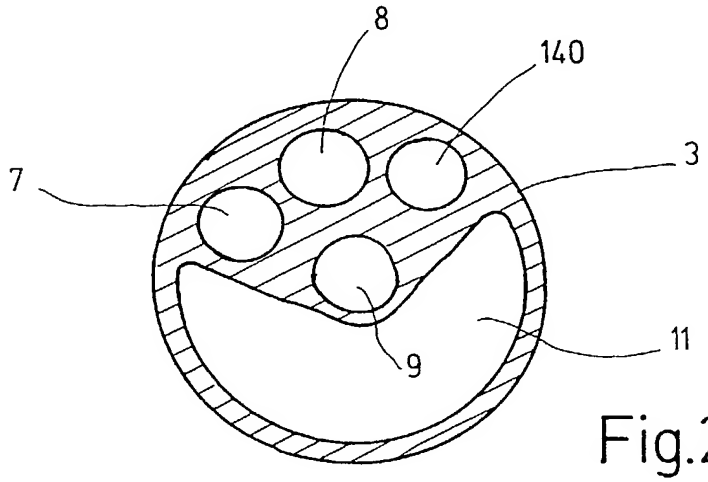

Fig.2

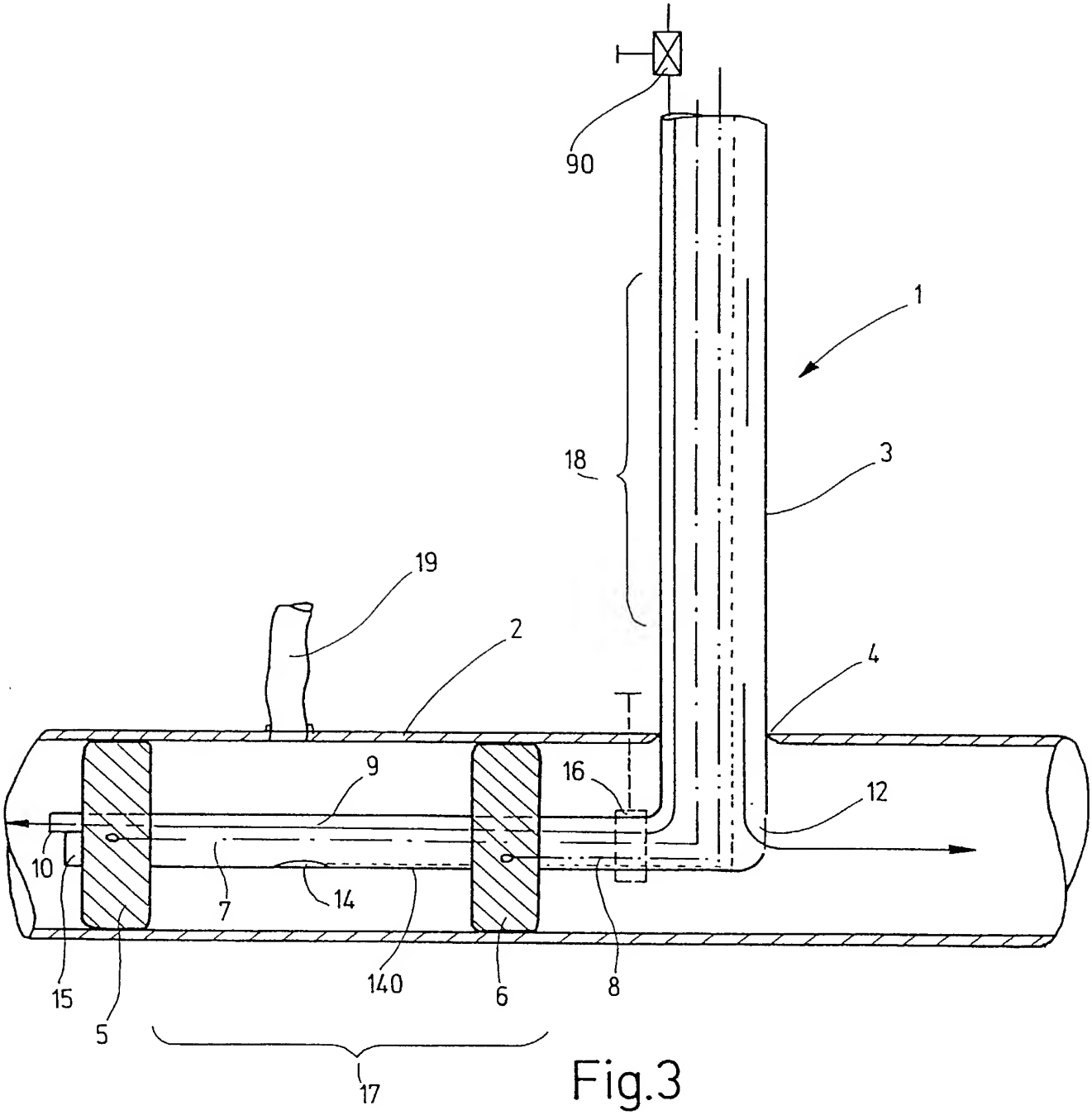

Fig.3

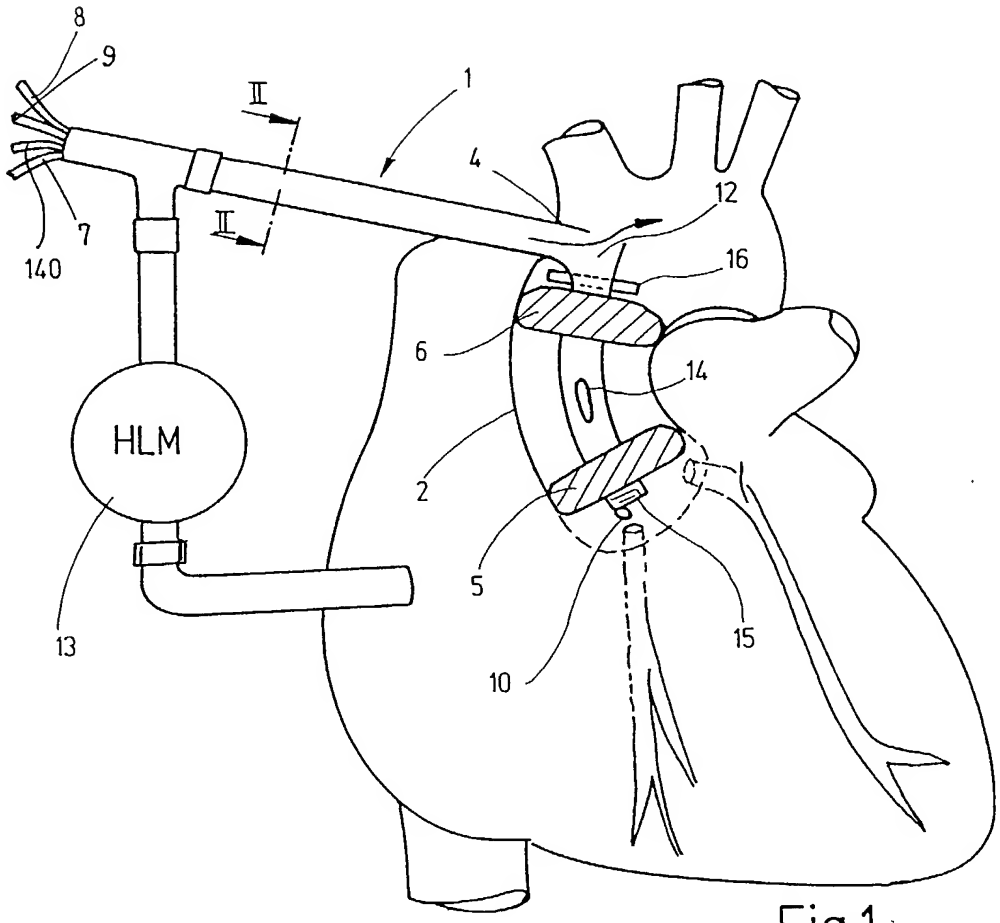

Fig.1

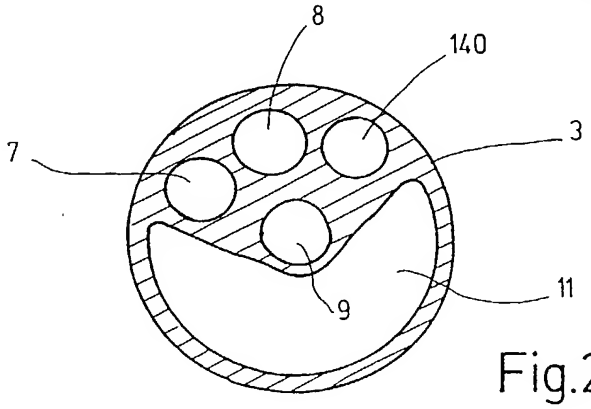

Fig.2

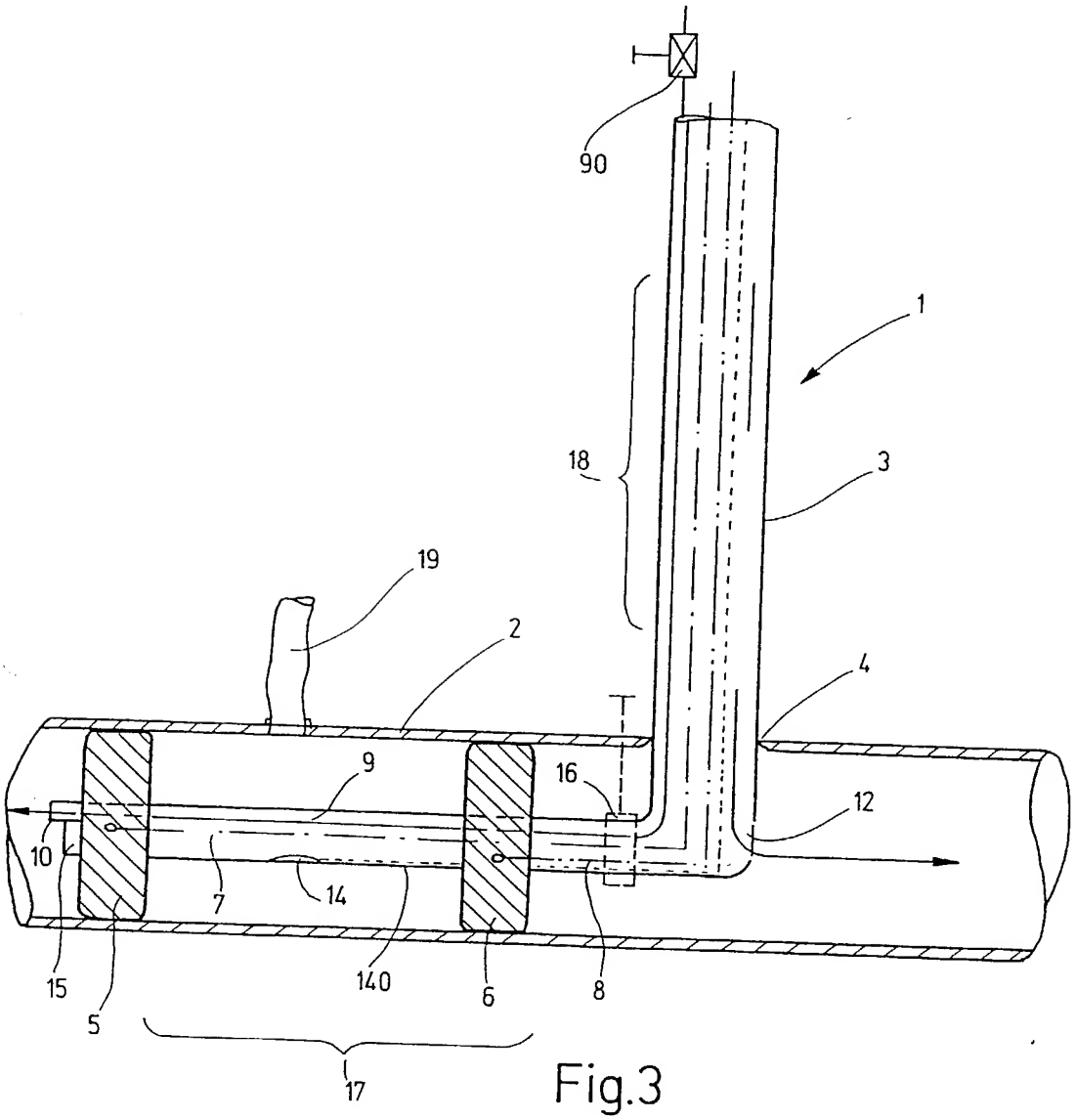

Fig.3

Rev. 11/00

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

PATENT

Docket No.: 47890/MEG/J191

As a below named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled AORTIC BALLOON OCCLUSION AORTA, the specification of which is attached hereto unless the following is checked:

_X_ was filed on September 12, 2000 as United States Application Number or PCT International Application Number PCT/DE00/03160 and was amended on March 13, 2002 __ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of the foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, any foreign application for patent or inventor's certificate, or any PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Application Number	Country	Filing Date (day/month/year)	Priority Claimed
99 117 905.2	Europe	13/09/1999	YES

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

Application Number	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112.

Application Number	Filing Date	Patented/Pending/Abandoned

POWER OF ATTORNEY: I hereby appoint the following attorneys and agents of the law firm CHRISTIE, PARKER & HALE, LLP to prosecute this application and any international application under the Patent Cooperation Treaty based on it and to transact all business in the U.S. Patent and Trademark Office connected with either of them in accordance with instructions from the assignee of the entire interest in this application;

DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION

Docket No. 47890/MEG/J191

or from the first or sole inventor named below in the event the application is not assigned; or from __ in the event the power granted herein is for an application filed on behalf of a foreign attorney or agent.

55

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I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Docket No. 47890/MEG/J191

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